

Message Text

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PAGE 01 STATE 031078
ORIGIN HEW-06

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FM SECSTATE WASHDC
TO AMEMBASSY MADRID

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E.O. 11652: N/A

TAGS: ECEM, SWEL, TBIO, SP

SUBJECT: SPANISH REQUEST FOR ASSISTANCE; SHORTAGE OF
DIABETES MEDICATION -

REF: MADRID 670

1. FDA ADVISES EMBASSY TO INFORM SPANISH HEALTH AUTH-
ORITIES OF THE FOLLOWING:

PITRESSIN TANNATE PREPARATIONS - THERE ARE TWO PREPARATIONS
CURRENTLY BEING MARKETING BY PARKE, DAVIS AND CO., IN THE
UNITED STATES. PITRESSIN TANNATE IN OIL IS THE SUBJECT OF
AN APPROVED NEW DRUG APPLICATION (NDA) NO. 3402. IT IS
APPROVED FOR USE IN THE CONTROL OR PREVENTION OF THE
SYMPTOMS AND COMPLICATIONS OF DIABETES INSIPIDUS DUE TO A
DEFICIENCY OF ENDOGENOUS POSTERIOR PITUITARY ANTIDIURETIC
HORMONE. PITRESSIN TANNATE, AQUEOUS IS NOT, REPEAT NOT,
THE SUBJECT OF AN APPROVED NDA ALTHOUGH DRUG IS MARKETING
IN THE UNITED STATES AND IS USED EXTENSIVELY FOR CONTROL
OF GASTROINTESTINAL BLEEDING.

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2. THE SPONSOR HAS DEVELOPED AND IS INTERESTED IN
MARKETING SYNTHETIC PREPARATIONS STATING THAT THE
SYNTHETIC PITRESSIN TANNATE (ARGININE VASOPRESSIN) WILL
BE MANUFACTURED BY ESSENTIALLY THE SAME PROCESS AS IS
CURRENTLY UTILIZED IN THE PREPARATION OF THE DRUG FROM
POSTERIOR PITUITARY GLAND DERIVED FROM SLAUGHTERED ANI-

MALS. THE SPONSOR HAS STATED THAT THE SYNTHETIC MATERIAL IN ADDITION TO SOLVING THE INTERNATIONAL SUPPLY PROBLEM HAS HIGH POTENCY, GREATER PURITY, AND IS COMPARABLE TO THE NATURAL VASOPRESSIN OF MAN. THE SYNTHETIC ARGENINE VASOPRESSIN WAS CHOSEN BY PARKE, DAVIS AS IT APPEARS TO HAVE A BETTER STABILITY PROFILE THAN LYSINE VASOPRESSIN. NOTE: NATURAL HORMONE CONSISTS OF BOTH ARGININE AND LYSINE VASOPRESSIN.

3. SYNTHETIC PITRESSIN TANNATE IN OIL IS THE SUBJECT OF INVESTIGATIONAL NEW DRUG APPLICATION (IND) NO. 11, 190. FDA APPROVED PRELIMINARY CLINICAL TRIALS ON AUGUST 12, 1975. A PROGRESS REPORT WAS SUBMITTED ON NOVEMBER 19, 1976. AN APPROVED NDA WILL BE REQUIRED BEFORE IT MAY BE MARKETING IN THE U.S.

4. SYNTHETIC PITRESSIN AQUEOUS INJECTION IS THE SUBJECT OF INVESTIGATIONAL NEW DRUG APPLICATIONS (IND) 12, 211 WHICH WAS MADE EFFECTIVE MAY 18, 1976. BASED ON PRESENT THERAPEUTIC REGIMENS, FDA HAS REQUESTED THAT AN APPROVED NDA BE OBTAINED FOR BOTH THE NATURAL AND SYNTHETIC PITRESSIN AQUEOUS INJECTION PRODUCTS. AT THE SAME TIME THE LABELING WILL BE REVISED AND THE NEW INDICATION FOR THE TREATMENT OF GASTROINTESTINAL BLEEDING MAY BE APPROVED.

5. SHORTAGE OF NATURAL PITRESSIN TANNATE IS WORLD-WIDE AND FDA AND FIRM ARE WORKING IN CLOSE CONJUNCTION TO APPROVE SYNTHETIC PRODUCTS AS SOON AS POSSIBLE WHILE UNCLASSIFIED

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ADHERING TO THE REQUIREMENTS OF THE FOOD, DRUG AND COSMETIC ACT.
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